the neuropsychiatric and personality profile of MS patients: its determinants and impact on daily life functioning. An extension of the FuProMS Study

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(1) to establish the neuropsychiatric and personality status (symptoms and impairments) (2) to assess the possible determinants of these symptoms and impairments and (3) to examine the impact of these symptoms and impairments on daily life...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40157

Source
ToetsingOnline

Brief title
NEUROPSYCHIATRIC CHANGES AND DAILY LIFE FUNCTIONING IN MS PATIENTS

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DAILY LIFE FUNCTIONING, MS, NEUROPSYCHIATRY

Outcome measures

Primary outcome

(1) difference in frequency of self-reported neuropsychiatric symptoms / disorders and personality characteristics between patients and controls using the following questionnaires: CES-D, HADS, CNS-LS, PDI-21, MDQ-NL and EPQ-RSS

(2) determinants of neuropsychiatric symptoms / disorders: biological markers (MRI parameters, family history), disease-related (including EDSS, fatigue, cognitive functioning and iatrogenic) and individual and psychosocial factors (demographic, locus of control, coping style, social support and premorbid personality)

(3) the impact of neuropsychiatric symptoms / disorders on daily life functioning measured by the FIM and SF-36

Secondary outcome

not applicable

Study description

Background summary

Neurobehavioral changes, in different levels of severity, are common in MS patients and pose a significant burden on quality of life and daily life functioning, but have been investigated incompletely. Although neuroimaging data offer important clues as to the pathogenesis of these abnormalities, psychosocial factors cannot be ignored and emerge as equally important predictors. Most likely, a complex interplay of biological, illness-related,

behavioral and psychosocial factors contribute to the pathophysiology of most of them.

Study objective

(1) to establish the neuropsychiatric and personality status (symptoms and impairments)
(2) to assess the possible determinants of these symptoms and impairments and
(3) to examine the impact of these symptoms and impairments on daily life functioning in a longitudinal cohort of patients with clinically diagnosed MS

Study design

Prolongation of a prospective longitudinal study.

Consists of the following two parts:
1. prospective observational part: to assess determinants of neuropsychiatric symptoms/disorders and their impact on daily functioning in MS patients
2. case-control cross-sectional part: comparison of frequencies of neuropsychiatric symptoms/disorders in patients vs controls

Study burden and risks

participants will need to fill in a number of self-report questionnaires and will receive one phone call to assess two questionnaires. Hence, no visit to the research centre/hospital is required. Estimated duration: 2 hours to fill in the self-reported questionnaires and an additional * hour for the assessment by telephone. No risk involved, no invasive techniques.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients: definite diagnosis of MS, recruited between 1998-2000, participants in the FuProMS study at the last wave
Controls: people aged 30 to 70 years, same catchment area as the patient base.

Exclusion criteria

Patients: no exclusion criteria
Controls: neurological disorder affecting the CNS.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2014
Enrollment:	333
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46666.029.13